

**The Mission of the Product Testing Laboratory is to provide our collaborators with accurate and timely information through optimal use of technology and resources.**

**Technicians:**

**Are responsible for the integrity of the test.  
They ensure the correct and consistent testing/calibration process utilizing established procedures.**



**Technical Leaders:**

**Are responsible for the integrity of the test results from their laboratory.  
They ensure results have been reviewed for consistency utilizing established procedures.**



**Receiving & Reporting:**

**Is responsible for the data integrity of the sample/request.  
They provide a final check of our process and ensure all the test results for a sample correctly reflect the sample received.**

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**Technicians:**

**Are responsible for the integrity of the test.**

**They ensure the correct and consistent testing/calibration process utilizing established procedures.**

**Accountabilities**

- Ensure correct & consistent calibration & testing based on procedures, work instructions, checklists & control charts.
- Ensure correct sample is tested & all associated analyses are requested.
- Review test results.  
Reject and recheck results.

**Recommendations**

- Use work instructions at test stations (use will be audited and documented).\*  
Follow control chart guidelines.\*
- Compare to paperwork.\*
- **Do not compare to Standard Deviation Limits.**
- Review data for too few # reps & inconsistent numbers.  
**Inconsistent numbers are a flag to look for an assignable cause, not criteria to recheck or reject.**
- **Reject data for assignable cause**, based on objective, defensible guidelines.\*
- Document rejected data in computer notes editing.\*
- Initiate recheck only if assignable cause indicates that data are invalid.

**They ensure results have been reviewed for consistency utilizing established procedures.**

## Recommendations

- Review data that have been through ADAP\* & are not automatically approved due to:  
high sd\*, outliers, incorrect # reps, or missing values,  
utilizing Status 50 & ToDo\* reports.

① investigated for assignable cause

- ② rechecked if:
  - assignable cause (or strong evidence) found, or
  - too few # reps, or
  - sd>2 x sd limit, to confirm
- ③ else it is approved.

- Request recheck (original values automatically rejected)  
Enter in notes editing recheck reason & assignable cause, if applicable  
Enter recheck info into lab notebooks.

① review results\*

- ② recheck & document if assignable cause found (not for sd)
- ③ else it is approved

- Review at least twice a year\*
- Watch techs perform test after review to ensure procedural

accuracy & document compliance.

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ATTACHMENT 4

**Receiving & Reporting:****Is responsible for the data integrity of the sample/request.****They provide a final check of our process and ensure all the test results for a sample correctly reflect the sample received.****Accountabilities**

- Utilize knowledge of products, programs/projects & procedures
- Ensure accuracy of sample submissions (entry, samples/tests, barcodes, etc.)
- Ensure timeliness of completion
- Ensure integrity of sample/request data, **not product-**  
Review Preliminary Report

**Recommendations**

- Stay current on procedures, work instructions, business awareness, collaborator communications
- Accurately capture quantity, priority, collaborator information, special instructions
- Monitor request in process (due dates vs. test completion)

**SD Warnings:**If  $sd > 2 \times sd \text{ limit}$ 

- Available information may confirm, or
- If already rechecked\*, sd is confirmed, or
- If not rechecked
  - Investigate for assignable cause (sample mix-ups, system errors)
  - If enough sample, recheck

**Assessing Averages:**

Target Guidelines\* - sample accuracy, and/or

Historical Data Results (hist. avg.  $\pm 2$  hist. sd) - process trend, or

Neither (dcv) - based on collaborator info, cigt construction knowledge

**Inter-relationships between tests:** (May confirm issues observed above)

If inter-relationships between tests do not explain questionable averages

- Available information may confirm, or
- If already rechecked, average is confirmed, or
- If not rechecked
  - Investigate for assignable cause (sample mix-ups, system errors)
  - If enough sample, recheck
- Contact collaborator if appropriate (based on program)